UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,342	12/31/2003	Jeffry G. Weers	53311-US-CNT	7605

1095 7590 10/22/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
10/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/751,342	WEERS ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,18-20,23-25,28-31,38-40,63-78,98,99 and 101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,18-20,23-25,28-31,38-40,63-78,98,99 and 101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of September 29, 2009 made to the office action filed May 26, 2009. Claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-78, 98, 99 and 101 are pending. Claims 1, 23, 63, 98, 99 and 101 are amended and claims 97 and 100 are cancelled.

In light of the cancellation of claim 100, the previous 35 U.S.C. 112 rejection is withdrawn.

In light of the Applicant's arguments being persuasive, the previous 35 U.S.C. 103(a) rejection are withdrawn. Specifically, Ponikau does not teach the treatment of a fungal infection, but of a treatment of a non-invasive fungus-induced mucositis.

The Examiner acknowledges Applicant's indication that a terminal disclaimer will be filed upon identification of allowable subject matter to obviate the provisional obviousness-type double patenting rejections over U.S. Patent Application No. 11/187,757. However, as such terminal disclaimers have not as-yet been filed, the provisional obviousness-type double patenting rejections over these co-pending applications are being maintained.

Due to the withdrawal of the previous 35 U.S.C. 103(a) rejection the new rejections are made below, which constitutes a new NON-FINAL rejection. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15, 18-20, 23-25, 28-31, 38-40, 98 and 99 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-

25, 27-30, 35-44 of copending Application No. 11/187,757 ('757) in view of Straub et al. (US 6,395,300 B1) in further view of Schmitt et al. (US 4,950,477). Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Application '757 teaches a method for treating a patient suffering from a fungal infection of the lung, comprising administering to the patient a therapeutically effective amount of a pharmaceutical formulation comprising a lipid matrix and at least one particle of an antifungal agent in the lipid matrix wherein the aerosolized (see claim 35) pharmaceutical formulation is for pulmonary administration (see claim 45) via inhalation (see claims 23 and 27). For clarification, the application '757 defines treating as providing prevention of a particular condition (see page 2, paragraph 26, lines 6-8). The lipid matrix comprises a phospholipid (see claim 7). The composition can be a dry powder that has a bulk density of less than 0.5 g/cm^3. The antifungal agent is amphotericin B (see claims 29 and 30). The amount of antifungal agent is at least twice the minimum inhibitory concentration of the antifungal agent for at least one week (see claim 35), three weeks or three months (see claims 39-42). Thus, determining the minimum inhibitory concentration is taught Tarara et al. because in order to administer twice the minimum inhibitory concentration, the minimum inhibitory concentration of the antifungal agent needs to be determined. The minimum inhibitory concentration is in the epithelial lining or the solid tissue of the lung (see claims 36 and 37), with a lung

concentration at least 9 μg/g or in the range of 9 μg/g to 15 μg/g (see claims 43 and 44). No active agent is detectable in the patient's serum or organs subsequent to administration of the formulation (see claims 31-34). The minimum inhibitory concentration is the minimum inhibitory concentration in the epithelial lining or solid tissue of the lung (see claims 36 and 37).

The application '757 does not teach a single dose or two doses of the pharmaceutical formulation during the first week of administration (claims 8 and 9). The two period administration wherein the antifungal agent is administered more frequently or at a higher dosage during the first period than during the second period is also not taught (claim 10). Neither is the administration comprising delivering the formulation periodically to maintain the antifungal agent lung concentration taught (claim 13). '757 also does not teach that the powder is a porous particle (claims 1 and 23), or that the specific fungal infection treated is aspergillosis (claims 23, 98 and 99).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of '757 and the administration detailed above in the applicant's claims 8, 9, 10 and 13 and determining the minimum inhibitory concentration of an antifungal agent for inhibiting pulmonary fungal growth because of the following: (1) the antifungal agent is administered for at least one week, three weeks or three months to maintain the twice the minimum inhibitory concentration (see claims 35 and 40); (2) it is within the art to administer a drug several times during a treatment. In order

to treat the fungal infection the antifungal agent must be present in concentrations that are effective. Whether the drug is administered once, twice, or several times, the important factor is that twice the minimum inhibitory concentration is maintained in the lungs.

Straub et al. teaches low aqueous solubility drugs such as the anti-fungal drug amphotericin B in a porous matrix form to provide a faster rate of dissolution following administration to a patient, as compared to non-porous matrix forms of the drug (see abstract, lines 1-2 and 15-18 and column 4, lines 47-48). The preferred embodiment is for oral administration using a dry powder inhaler for pulmonary administration (see column 3, lines 1 and 6-8).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of '757 and wherein the powder is porous because Straub et al. teaches that a porous matrix of the antifungal agent amphotericin B provides a faster rate of dissolution following administration to a patient as compared to non-porous forms of the drug (see abstract, lines 1-2 and 15-18 and column 4, lines 47-48).

Schmitt et al. teaches a method of treating pulmonary aspergillosis by administering amphotericin B in an aerosol spray (see abstract).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of '757 and wherein the specific fungal infection treated is aspergillosis because Schmitt et al. teaches that amphotericin B treats aspergillosis (see abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1) Claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-76, 98 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 2006/0159625 A1) in view of Straub et al. (US 6,395,300 B1) and Schmitt et al. (US 4,950,477).

The applied reference has a common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as application 11/187,757 (published as US 2006/0159625 A1) at the time this invention was made, or was subject to a joint research agreement at the time this invention was made. However, reference US 2006/0159625 A1 additionally qualifies as prior art under

another subsection of 35 U.S.C. 102, and therefore, is not disqualified as prior art under 35 U.S.C. 103(c).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

Tarara et al. teaches a method for treating a patient suffering from a fungal infection of the lung, comprising administering to the patient a therapeutically effective amount of a pharmaceutical formulation comprising a lipid matrix and at least one particle of an antifungal agent in the lipid matrix wherein the aerosolized (see claim 35) pharmaceutical formulation is for pulmonary administration (see claim 45) via inhalation (see claims 23 and 27). For clarification, Tarara et al. defines treating as providing prevention of a particular condition (see page 2, paragraph 26, lines 6-8). The lipid matrix comprises a phospholipid (see claim 7). The composition can be a dry powder that has a bulk density of less than 0.5 g/cm^3. The antifungal agent is amphotericin B (see claims 29 and 30). The amount of antifungal agent is at least twice the minimum inhibitory concentration of the antifungal agent for at least one week (see claim 35), three weeks or three months (see claims 39-42). Thus, determining the minimum inhibitory concentration is taught in application ‘757 because in order to administer twice the minimum inhibitory concentration, the minimum inhibitory concentration of the

antifungal agent needs to be determined. The minimum inhibitory concentration is in the epithelial lining or the solid tissue of the lung (see claims 36 and 37), with a lung concentration at least 9 μg/g or in the range of 9 μg/g to 15 μg/g (see claims 43 and 44). No active agent is detectable in the patient's serum or organs subsequent to administration of the formulation (see claims 31-34). The minimum inhibitory concentration is the minimum inhibitory concentration in the epithelial lining or solid tissue of the lung (see claims 36 and 37).

Tarara et al. does not teach a single dose or two doses of the pharmaceutical formulation during the first week of administration (applicant's claims 8 and 9). The two period administration wherein the antifungal agent is administered more frequently or at a higher dosage during the first period than during the second period is also not taught (see applicant's claims 10). Neither is the administration comprising delivering the formulation periodically to maintain the antifungal agent lung concentration taught (see applicant's claim 13). Tarara et al. also does not teach that the powder is a porous particle (claims 1 and 23), or that the specific fungal infection treated is aspergillosis (claims 23, 98 and 99).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Tarara et al. and the administration detailed above in the applicant's claims 8, 9, 10 and 13 and determining the minimum inhibitory concentration of an antifungal agent for inhibiting pulmonary fungal growth because of

the following: (1) the antifungal agent is administered for at least one week, three weeks or three months to maintain the twice the minimum inhibitory concentration (see claims 35 and 40); (2) it is within the art to administer a drug several times during a treatment. In order to treat the fungal infection the antifungal agent must be present in concentrations that are effective. Whether the drug is administered once, twice, or several times, the important factor is that twice the minimum inhibitory concentration is maintained in the lungs.

Straub et al. teaches low aqueous solubility drugs such as the anti-fungal drug amphotericin B in a porous matrix form to provide a faster rate of dissolution following administration to a patient, as compared to non-porous matrix forms of the drug (see abstract, lines 1-2 and 15-18 and column 4, lines 47-48). The preferred embodiment is for oral administration using a dry powder inhaler for pulmonary administration (see column 3, lines 1 and 6-8).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Tarara et al. and wherein the powder is porous because Straub et al. teaches that a porous matrix of the antifungal agent amphotericin B provides a faster rate of dissolution following administration to a patient as compared to non-porous forms of the drug (see abstract, lines 1-2 and 15-18 and column 4, lines 47-48).

Schmitt et al. teaches a method of treating pulmonary aspergillosis by administering amphotericin B in an aerosol spray (see abstract).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Tarara et al. and wherein the specific fungal infection treated is aspergillosis because Schmitt et al. teaches that amphotericin B treats aspergillosis (see abstract).

(2) Claims 1-15, 18-20, 23-25, 28-31, 38-40, 63-76, 98, 99 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weickert et al. (US 2002/0177562 A1) in view of Straub et al. (US 6,395,300 B1) and Schmitt et al. (US 4,950,477).

Weickert et al. teach a dry powder aerosolized polyene composition for oral inhalation to the lung to treat pulmonary and systemic fungal infections (see abstract; example 1; and page 10 paragraph 114; addresses claims 1, 20, 23, 40, 63, and 76) such as aspergillosis (see paragraph 125, addresses claims 23, 98 and 99). The composition comprise an antifungal agent such as amphotericin B (see example 1, addresses claims 11, 15, 23, 67, 71) in concentrations of about 0.01 mg/kg to about 7 mg/kg per dose 1 to 8 times daily over a course of from about 7 to about 183 days (see page 11, paragraph 127; addresses claims 1, 4-9, 12, 13, 23, 28, 29-31, 63, 66 and 68-70). Typically the composition it administered in doses that are 3-10 times or more

times the MIC of the causative fungal pathogen. Depending upon the particular antifungal compound, the condition being treated, the age and weight of the subject and the like, the dosage amount can vary (see page 11, paragraph 128, addresses claims 1, 12, 14, 23, 62 and 63). The compositions penetrate into the airways of the lungs and achieve effective concentrations in the infected secretions and lung tissue, including the epithelial lining fluid, alvelolar, macrophages, and neutrophils, typically exceeding the MIC's of most respiratory fungal pathogens (see paragraph 124, addresses claims 2, 3, 24, 25, 64 and 65). The composition may also contain phospholipids (see paragraph 83; addresses 18, 19, 38, 39, 74 and 75). The powder particle size is below 3.3 microns and a bulk density of from about 0.05 to 10 g/cubic centimeter (see paragraphs 112 and 113; addresses claims 1, 23 and 72). The aerosolized inhaler can be delivered in a variety of different devices that involve a valve to release the formulation (see paragraph 118-120; addresses claim 77), such as a pressurized metered dose inhaler containing a solution or suspension of the drug in a propellant such as CFC, HFC or fluorocarbon (see paragraph 121; addresses claim 78). The formulations are particularly useful for immunocomprised patients such as individuals undergoing chemotherapy, organ transplant recipients, or suffering from HIV (see paragraph 125, addresses claim 63).

Weickert et al. does not specifically teach wherein the pharmaceutical formulation comprises porous particles (claims 1, 23 and 73), or wherein the formulation is administered in a first dosage followed after a predetermined time interval by a

second dosage that is greater than the second dosage (claim 1). Weichert et al. also does not teach wherein the administration comprises a first administration period and a second administration period wherein the amphotericin B is administered more frequently or at a higher dosage during the first administration period than during the second administration period (claim 23). Weichert et al. also does not specifically teach the administration of an immunosuppressive agent (claim 63), or an administration comprising delivering at least two doses per week of the pharmaceutical formulation before the administration of the immunosuppressive agent and wherein the target concentration is maintained by administering doses of the pharmaceutical formulation less frequently as disclosed in claim 66. Weichert et al. also does not specifically teach that after two days following administration, a concentration of antifungal agent in the lungs is at least about 150 times a concentration of antifungal agent in the lungs delivered intravenously, and wherein a concentration of antifungal agent in the serum is substantially zero (claim 101). Weichert et al. also does not teach that the MIC was specifically determined (claims 1, 23 and 63)

Straub et al. teaches low aqueous solubility drugs such as the anti-fungal drug amphotericin B in a porous matrix form to provide a faster rate of dissolution following administration to a patient, as compared to non-porous matrix forms of the drug (see abstract, lines 1-2 and 15-18 and column 4, lines 47-48). The preferred embodiment is for oral administration using a dry powder inhaler for pulmonary administration (see column 3, lines 1 and 6-8). The matrix further includes a pegylated excipient, such as

pegylated phospholipic to shield the drug from macrophage uptake, which prolongs its half-life or enhance bioavailability of the drug (see column 2, lines 63-67). The density of the dry porous matrix powder is preferably less than 0.8 g/mL to provide sufficient surface area to enhance wetting of the dry porous matrix and enhance drug dissolution (see column 3, lines 65-66 and column 4, lines 2-5).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Weickert et al. and wherein the pharmaceutical formulation comprises hollow and/or porous particles within a matrix material that comprises one or more phospholipids because Straub et al. teaches the following: (1) drugs such as the anti-fungal drug amphotericin B in a porous matrix form to provide a faster rate of dissolution following administration to a patient, as compared to non-porous matrix forms of the drug (see abstract, lines 1-2 and 15-18 and column 4, lines 47-48); (2) the density of the dry porous matrix powder is preferably less than 0.8 g/mL to provide sufficient surface area to enhance wetting of the dry porous matrix and enhance drug dissolution (see column 3, lines 65-66 and column 4, lines 2-5); and (3) the matrix further includes a pegylated excipient, such as pegylated phospholipic to shield the drug from macrophage uptake, which prolongs its half-life or enhance bioavailability of the drug (see column 2, lines 63-67). Thus, it would be beneficial for the methods and compositions of Weickert et al. to comprise hollow and/or porous particles within a matrix material that comprises one or more phospholipids because of the reasons stated above.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Weickert et al. wherein the administration of the formulation is as those disclosed in claims 1, 23 and 63, or the specific dosage amounts disclosed in claims 12-14, 23 and 68-70 because of the following teachings: 1) Weickert et al. teach that depending upon the particular antifungal compound, the condition being treated, the age and weight of the subject and the like, the dosage amount can vary (see page 11, paragraph 128, addresses claims 1, 12, 14, 23, 62 and 63); and 2) It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it is within the skill of the art to design an administration schedule and or amounts depending on the information given above.

In regards to the administration of an immunosuppressant agent, it would be obvious to administer such an agent because Weickert et al. teach that the formulations are idea for those who are undergoing chemotherapy, organ transplant recipients, or suffering from HIV (see paragraph 125). Thus, since these patients are most likely taking immunosuppressant agents, it is within the skill of the art to determine a an administration schedule and or amounts depending upon the particular antifungal compound, the condition being treated, the age and weight of the subject and the like.

In regards to claim 101, the teaching of Ponikau in view of Straub et al. render these claims obvious because Ponikau teaches the applicant's administration method and Straub et al. teaches that applicant's claimed drug (amphotericin B) can be delivered in a porous aerodynamic powder via inhalation to the lungs. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established. Thus, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Therefore administering the same drug in the same manner will give the same properties.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K. D. C./
Examiner, Art Unit 1627

/Shengjun Wang/
Primary Examiner, Art Unit 1627